DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

September 7, 2018

National Freedom of Information Officer
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460

Dear FOIA Officer:

The Centers for Disease Control received the enclosed Freedom of Information Act request from Robert A. McMahon. Mr. McMahon is seeking a copy of all records pertaining to the article entitled Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants, authored by Richard Kanwal, MD., et al ("Kanwal Article").

Documents belonging to your agency are being referred to you for your review and direct response to the requester. A total of 2 pages are referred. CDC has no concerns with the release of any CDC equity on these pages.

We have advised the requester of this referral to your agency (CDC final response letter enclosed).

If you have any questions about this referral/consultation, please contact Emily Fitzgerald at 404-498-0511.

Sincerely,

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

Enclosures

CDC FOIA #15-00285-FOIA

Kanwal, Richard

From: Kanwal, Richard
Sent: Monday, November 03, 2003 8:59 AM
To: 'Rosati.Jacky@epamail.epa.gov'
Subject: RE: Popcorn Meeting next week

It's nice to hear that ConAgra may share information that could advance your work. As far as the workshop goes, we limited the invitees to just representatives of flavoring companies and popcorn companies because the flavoring companies were initially reluctant to attend a meeting that was "too open" to many different groups or individuals. I don't want any of them to complain that I invited someone from the EPA and did not let them know about this ahead of time. We wanted these individuals to feel free to take part in discussions. I did make one exception for a representative of a bag maker (Exopack) because the Popcorn Board let him know about the workshop. It has been difficult getting this workshop to happen, I think because of all the legal concerns the companies have. Tell Ken that I apologize for not being able to include him. Obviously I want to help in any way I can to facilitate the work you guys are doing.

-----Original Message-----
From: Rosati.Jacky@epamail.epa.gov [mailto:Rosati.Jacky@epamail.epa.gov]
Sent: Thursday, October 30, 2003 4:57 PM
To: Kanwal, Richard
Cc: krebs.ken@epamail.epa.gov
Subject: Popcorn Meeting next week

Hey Rich,

We were meeting with Jim Montelegra of Con-Agra and he mentioned that you guys were hosting a meeting next week. If we can swing it, would it be ok if Ken Krebs (co PI) attended? It might be beneficial for all. FYI ... we have been corresponding with Con-Agra and it looks like we now may be able to get quite a bit of info from them. This will be helpful for our experimental work (we won't be starting from scratch), and may benefit you also. Once we get some confidentiality issues worked out, we can have more knowledge of their experiments, field info, formulations, etc. and validate (??) what they have done.

Hope all is well with you.
Jacky

Jacky Ann Rosati, Ph.D.
Environmental Scientist
U.S. Environmental Protection Agency
Indoor Environment Management Branch
E-305-03, 109 T.W. Alexander Drive
Research Triangle Park, NC 27711
(919) 541-9429
Fax (919)541-2157
rosati.jacky@epa.gov

Kanwal, Richard

From: Rosati.Jacky@epamail.epa.gov
Sent: Monday, February 23, 2004 2:44 PM
To: Kanwal, Richard
Subject: Re: Reporter interview

Hi Rich-

Thanks for the heads up. Work is progressing, as are the talks with ConAgra (Working out a confidentiality agreement). I'll keep you updated.

Jacky

Jacky Ann Rosati, Ph.D.
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NIOSH
15-00285
12/13/14 - 1/23/15

Eberly McMahon Copetas LLC

David A. Eberly**
Robert A. McMahon*
Ted Copetas

Attorneys at Law

*Also admitted in Kentucky
**Also admitted in Indiana

Via Regular and Certified Mail, Return Receipt Requested

December 19, 2014

CDC/ATSDR
Attn: FOIA Office, MS: D54
1600 Clifton Rd, N.E.
Atlanta, GA 30333
FAX: (770) 488-6200
FOIARequests@cdc.gov

Department of Health and Human Services
Attn: Mr. Robert Eckert
FOIA Officer
Mary E. Switzer Building, Room 2221
300 C Street, SW
Washington, DC 20201
(202) 690-8320 (Fax)

Re: Freedom of Information Act Request

To Whom It May Concern:

Pursuant to the Freedom of Information Act, 5 U.S.C. §552 ("FOIA"), I hereby request the production of or the opportunity to inspect and/or copy any and all documents, files, records and other information and materials in the possession of the United States Department of Health and Human Services ("DHHS"), Centers for Disease Control and Prevention ("CDC"), the Agency for Toxic Substances and Disease Control ("ATSDR"), and the National Institute for Occupational Safety and Health ("NIOSH") or their respective regional offices concerning, discussing, relating to, or referring to the article entitled Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants, authored by Richard Kanwal, M.D., et al ("Kanwal Article"). Specifically, I am requesting copies of all documentation, data and correspondence (electronic and hard copy) relating to or comprising the "backup" for the Kanwal Article. By "backup," by way of example, and without limiting my request, I am requesting the underlying documentation, data, or correspondence (electronic and hard copy) that support or are referenced in the following statements in the Kanwal Article:

- "A NIOSH cross-sectional medical and environmental survey at Plant A (the index plant) revealed an elevated prevalence of obstructive lung disease that was associated with cumulative exposure to diacetyl, the predominant butter-flavoring chemical in the air of the plant." (p. 149)

- "In experiments conducted at NIOSH, rats exposed to vapors from a butter flavoring used at this plant developed severe injury of their airway epithelium. Rats developed similar airway damage (although less extensive) with inhalation of vapors of pure diacetyl." (p. 149)

- "Similar lung disease has also occurred in workers at flavoring manufacturing plants." (p. 149).

- "Of the six evaluations, two were requested by management, two by state health departments, and two by workers." (p. 150)

- "NIOSH interviewers administered a questionnaire to collect information on symptoms, medical diagnoses, smoking history, work history, and work-related exposures." (p. 150).

- "Using a dry rolling-seal spirometer interfaced to a computer, NIOSH technicians performed spirometry tests following American Thoracic Society guidelines with results compared with spirometry reference values generated from the Third National Health and Nutrition Examination Survey (NHANES III)." (p. 150).

- "We aggregated the medical survey data from all six plants and used SAS software (SAS version 9.1, 2002-2003; SAS Institute, Inc., Cary, NC) for statistical analyses." (p. 150).

- "Some workers . . . gave consent for us to review their medical records. . . . We also reviewed available lung biopsy reports if biopsies had been performed." (p. 150).

- "As an indicator of exposure to butter-flavoring chemicals, we measured full-shift time-weighted average (TWA) air concentrations of diacetyl in several areas of each plant with sorbent tubes and gas chromatography according to NIOSH Method 2557." (p. 150)

- "At most plants, we also obtained personal exposure measurements for diacetyl with sampling equipment located on the worker." (p. 150)

- "At one plant, we used a Gasmet DX-4010 Fourier Transform Infrared (FTIR) Gas Analyzer . . . to measure real-time concentrations of diacetyl in a worker's breathing zone while he handled open containers of butter flavorings." (p. 150)

- "In each plant, one to three workers per work shift (i.e., mixers) measured butter flavorings (liquids, pastes, and powders) in open containers such as 5-gallon buckets and

poured the flavoring into heated soybean oil in large (eg, 500-gallon) heated mixing tanks, most of which had loose-fitting lids." (p. 150)

- "visible plumes of vapors were often apparent when tank lids were opened. . . ." (p. 150)
- "Compared with the index plant, mean diacetyl air concentrations in the mixing areas at the other five plants were generally one to two orders of magnitude lower (Table 1)." (p. 151).
- "In four of these five other plants, the highest TWA diacetyl air concentration measured with area sampling in mixing areas was between 0.6 and 1.0 parts per million (ppm) compared with 98 ppm at the index plant." (p. 151).
- "In Plant F, the highest TWA diacetyl air concentration measured with area sampling in the mixing room was 2.7 ppm, just slightly above the lowest mixing room TWA diacetyl air concentration in the index plant." (p. 151)
- "In five of the six plants, packaging areas had lower mean diacetyl air concentrations than mixing areas." (p. 151).
- "Compared with the index plant, mean diacetyl air concentrations in the packaging areas of all other plants were much lower (Table 1)." (p. 151).
- "The lowest TWA diacetyl air concentration measured with area sampling in the packaging areas of plants B through F ranged from below the limit of detection (0.001 ppm) in plant D to 0.4 ppm in plant B. The highest TWA diacetyl air concentration measured with area sampling ranged from 0.03 ppm in plants D and F to 1.2 ppm in plant B (compared with 6.8 ppm in the index plant)." (p. 151).
- "In addition to the four known affected mixers and four known affected packaging-line workers among former workers of the index plant (plant A), medical records documented that an additional worker at plant A with past mixing experience, mixers at plants B, D, and F (one at each plant), and three packaging-line workers at plant E had fixed airways obstruction, normal diffusing capacity, and evidence of air trapping on chest CT scans." (p. 152).
- "Of the lung biopsy reports we reviewed, two of three workers biopsied from plant A and three of six workers biopsied from plant E had findings consistent with constrictive bronchiolitis obliterans." (p. 152).
- ". . . ever-mixers had higher prevalences of all respiratory symptoms with statistically significant excesses for SOB 2, chronic cough, and wheezing (Table 3)." (p. 152).
- "The mean percent predicted FEV1 was 89% in ever-mixers and 94% in never-mixers. . . ." (p. 152).

- "Nine of the 10 ever-mixers with obstruction had a bronchodilator administered; eight of the nine (89%) had fixed obstruction." (p. 152).
- Tables 2 and 3 (p. 153).
- "Compared with packaging-area workers in plants with isolated tanks, packaging-area workers in plants with nonisolated or inadequately isolated tanks had higher prevalences of all respiratory symptoms and airways obstruction; . . ." (p. 153-154).
- Table 4 (p. 154).
- "Five of six QC workers tested (85%) had airways obstruction at plant A, which clearly had the highest QC laboratory mean diacetyl air concentration (0.6 ppm). No other plant had high rates of obstruction in QC workers." (p. 154).
- ". . . maintenance workers had higher prevalences of all respiratory symptoms . . ." (p. 154).
- Table 5 (p. 155).
- "The investigation of severe fixed obstructive lung disease in workers of a microwave popcorn plant in 2000 identified inhalation exposure to butter-flavoring chemicals as the likely cause." (p. 155).
- "Our analyses of aggregated data from medical and environmental surveys at the index plant and five additional microwave popcorn plants indicate an apparent widespread risk for occupational lung disease from exposure to butter-flavoring chemicals in this industry." (p. 155).
- "In five of six plants, mixers and/or packaging-area workers with onset of respiratory symptoms after starting work had undergone medical evaluations that revealed fixed airways obstruction and other findings consistent with bronchiolitis obliterans." (p. 155).
- "Mixers at four of six plants had medical findings consistent with bronchiolitis obliterans . . ." (p. 155).
- ". . . even when ventilation maintains low-average exposures, mixers are still at risk from brief, intense exposure associated with open handling of butter flavorings or opening lids to check on tanks of heated oil and flavorings." (p. 155-156).
- "Packaging-area workers near nonisolated tanks that contain heated oil and flavorings are likely at risk from higher average concentrations of flavoring chemicals in the air or from intermittent peak exposures when mixers add butter flavorings to tanks or lift tank lids to check on the contents." (p. 156).

- "The high prevalence of airways obstruction in QC workers at plant A implies that this job can pose risk when many dozens of bags are popped daily without adequate control of exposures. . . . However, the much higher temperatures that occur in microwave popping (compared with the temperatures in heated tanks) increase the volatilization of other chemicals. Because of this QC workers' exposures may be substantially different from those of other production workers, and diacetyl air concentrations alone may not be a satisfactory predictor of risk for these workers." (p. 156).

- "Of an estimated 425 former workers who worked at plant A between 1992 and 2000, only 161 (approximately 38%) participated in our survey. Because of this low participation and the possibility that this was not a representative sample of former workers, we did not include this group in our analyses. . . ." (p. 156).

- "At this time, insufficient data exist on which to base workplace exposure standards or recommended exposure limits for butter flavorings." (p. 156).

- "because flavorings are complex mixtures of many chemicals, most of which have not been evaluated with respect to inhalation toxicity, focusing solely on diacetyl air concentrations may not be adequate to assess risk in different plants using a variety of different flavorings." (p. 156).

- "Encapsulated powdered flavorings that release less flavoring-related vapors into the air may be a safer alternative to liquid and paste flavorings." (p. 157).

We also request the following:

1. Any and all data and documents submitted in connection with the peer review process for the Kanwal Article.

2. Any and all communications between DHHS, CDC, ATSDR or NIOSH or their respective agents, employees or representatives and the American College of Occupational and Environmental Medicine regarding the Kanwal Article.

3. Any and all inspections, investigations, evaluations, studies, reports, analyses, sampling, sampling data, files, questionnaires, measurements, pulmonary function tests ("PFT") (including but not limited to PFT results and all documents related to PFTs) or surveys (including but not limited to medical, environmental, and/or industrial hygiene), conducted by or on behalf of DHHS, CDC, ATSDR or NIOSH of the six plants that were the subject of the Kanwal Article.

4. Any and all correspondence, memoranda, meeting notes, or communications prepared at any time from 2000 to the present regarding any of the six plants that were the subject of the Kanwal Article or employees or former employees of the six plants.

5. Any and all photographs, videos, drawings, charts, and graphs regarding the six plants.

6. Any and all notices of violations, citations, and penalty notices issued by DHHS, CDC, ATSDR or NIOSH to any of the six plants,

7. Any and all records relating to the employees and former employees of the six plants who were the subject of investigation, evaluation, test or study, including but not limited to, medical records, medical histories, employment histories, job descriptions and occupational exposure histories.

8. All communications between DHHS, CDC, ATSDR or NIOSH or their respective agents, employees or representatives and any physician or other medical professional who examined, treated, consulted with or reviewed records of any employee or former employee of the six plants.

9. Any and all complaints, grievances, inquiries, or reports made, directed, forwarded to, or received by the DHHS, CDC, ATSDR or NIOSH related to the six plants.

10. Any and all correspondence or evidence of other communications (including but not limited to email, notes of conversations, and phone logs) between DHHS, CDC, ATSDR or NIOSH or their respective agents, employees, or representatives and any lawyer, doctor, or expert witness involved in or previously involved in litigation relating to diacetyl and/or butter flavoring at any time from 2000 to the present, including but not limited to David Egilman, M.D., Alan Parmet, M.D., Charles Pue, M.D., or Kenneth McClain, Esq. (or any other person affiliated with Humphrey Farrington & McClain).

11. Any and all records relating to long-term studies, follow-up investigations, evaluations, tests, studies, reports (including drafts and supporting or backup documentation or data) conducted by or on behalf of the DHHS, CDC, ATSDR or NIOSH of any popcorn plant worker, including but not limited to the employees or former employees of the six plants.

Under applicable law pertaining to the Freedom of Information Act, the above-requested information is available to us and other members of the public. In the event DHHS, CDC, ATSDR or NIOSH or their respective representatives withhold any part of the information requested above, please provide the undersigned with a written explanation regarding the reason and legal basis for such withholding and describe 1) the type of information withheld; 2) the date(s) of creation; 3) the subject matter; 4) the identity of the author and all recipients; 5) the names of all people, entities, and locations referenced.

I look forward to your anticipated cooperation and to hearing from you within the twenty (20) day statutory period during which you must respond to this request. I confirm in advance my willingness to pay for all reasonable costs associated with copying the requested information. However, if the costs will exceed $500.00, please contact me first to discuss. Please contact me with any questions at 513-533-3441. Otherwise, please forward all responsive documents to:

Robert A. McMahon, Esq.
Eberly McMahon Copetas LLC
2321 Kemper Lane, Suite 100
Cincinnati, OH 45206

Thank you for your prompt attention to this matter.

Very Truly Yours,

Robert A. McMahon

Eberly McMahon Copetas LLC
Attorneys at Law

2321 Kemper Lane
Suite 100
Cincinnati, Ohio 45206

CDC/ATSDR
Attn: FOIA Office, MS: D54
1600 Clifton Rd, N.E.
Atlanta, GA 30333

Aquino, Lita (CDC/NIOSH/OD)

From: FOIA Requests (CDC)
Sent: Tuesday, December 23, 2014 2:39 PM
To: NIOSH FOIA Requests (CDC)
Cc: Aquino, Lita (CDC/NIOSH/OD); Fitzgerald, Emily (CDC/NIOSH/OD)
Subject: 12/23/2014 Recieved Mail
Attachments: 20141223144047488.pdf

-----Original Message-----
From: FOIA Requests (CDC)
Sent: Tuesday, December 23, 2014 2:41 PM
To: Brown, Dephine (CDC/OCOO/OCIO)
Subject:

This E-mail was sent from "RNPAD613B" (Aficio MP 5500).

Scan Date: 12.23.2014 14:40:47 (-0500)
Queries to: foiarequests@cdc.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

September 6, 2018

Robert A. McMahon
Eberly McMahon LLC
2321 Kemper Lane, Suite 100
Cincinnati, Ohio 45206

Dear Mr. McMahon:

This letter is regarding to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of December 23, 2014, assigned #15-00285-FOIA, for any and all documents, files, records and other information and materials discussing, relating to, or referring to the article entitled "Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants," authored by Richard Kanwal, M.D., et al ("Kanwal Article"), to include all documentation, data and correspondence relating to or comprising the "backup" for the Kanwal Article. Specifically, you requested the underlying documentation, data, or correspondence that support or are referenced in the following statements in the Kanwal Article:

- "A NIOSH cross-sectional medical and environmental survey at Plant A (the index plant) revealed an elevated prevalence of obstructive lung disease that was associated with cumulative exposure to diacetyl, the predominant butter-flavoring chemical in the air of the plant." (p. 149)

- "In experiments conducted at NIOSH, rats exposed to vapors from a butter flavoring used at this plant developed severe injury of their airway epithelium. Rats developed similar airway damage (although less extensive) with inhalation of vapors of pure diacetyl." (p. 149)

- "Similar lung disease has also occurred in workers at flavoring manufacturing plants." (p.149)

- "Of the six evaluations, two were requested by management, two by state health departments, and two by workers." (p. 150)

- "NIOSH interviewers administered a questionnaire to collect information on symptoms, medical diagnoses, smoking history, work history, and work-related exposures." (p. 150)

- "Using a dry rolling-seal spirometer interfaced to a computer, NIOSH technicians performed spirometry tests following American Thoracic Society guidelines with results compared with spirometry reference values generated from the Third National Health and Nutrition Examination Survey (NHANES III)." (p. 150)

- "We aggregated the medical survey data from all six plants and used SAS software (SAS version 9.1, 2002-2003; SAS Institute, Inc., Cary, NC) for statistical analyses." (p. 150)

- "Some workers ... gave consent for us to review their medical records .... We also reviewed available lung biopsy reports if biopsies had been performed." (p. 150).

- "As an indicator of exposure to butter-flavoring chemicals, we measured full - shift timeweighted average (TWA) air concentrations of diacetyl in several areas of each plant with sorbent tubes and gas chromatography according to NIOSH Method 2557." (p. 150)

- "At most plants, we also obtained personal exposure measurements for diacetyl with sampling equipment located on the worker." (p. 150)

- "At one plant, we used a Gasmet DX-4010 Fourier Transform Infrared (FTIR) Gas Analyzer… to measure real-time concentrations of diacetyl in a worker's breathing zone while he handled open containers of butter flavorings." (p. 150)

- "In each plant, one to three workers per work shift (i.e., mixers) measured butter flavorings (liquids, pastes, and powders) in open containers such as 5-gallon buckets and poured the flavoring into heated soybean oil in large (eg, 500-gallon) heated mixing tanks, most of which had loose-fitting lids." (p. 150)

- "visible plumes of vapors were often apparent when tank lids were opened…" (p. 150)

- "Compared with the index plant, mean diacetyl air concentrations in the mixing areas at the other five plants were generally one to two orders of magnitude lower (Table 1)." (p. 151)

- "In four of these five other plants, the highest TWA diacetyl air concentration measured with area sampling in mixing areas was between 0.6 and 1.0 parts per million (ppm) compared with 98 ppm at the index plant." (p. 151)

- "In Plant F, the highest TWA diacetyl air concentration measured with area sampling in the mixing room was 2.7 ppm, just slightly above the lowest mixing room TWA diacetyl air concentration in the index plant." (p. 151)

- "In five of the six plants, packaging areas had lower mean diacetyl air concentrations than mixing areas." (p. 151)

- "Compared with the index plant, mean diacetyl air concentrations in the packaging areas of all other plants were much lower (Table 1)." (p. 151)

- "The lowest TWA diacetyl air concentration measured with area sampling in the packaging areas of plants B through F ranged from below the limit of detection (0.001 ppm) in plant D to 0.4 ppm in plant B. The highest. TWA diacetyl air concentration measured with area sampling ranged from 0.03 ppm in plants D and F to 1.2 ppm in plant B (compared with 6.8 ppm in the index plant)." (p. 151)

- "In addition to the four known affected mixers and four known affected packaging-line workers among former workers of the index plant (plant A), medical records documented that an additional worker at plant A with past mixing experience, mixers at plants B, D, and F (one at each plant), and three packaging-line workers at plant E had fixed airways obstruction, normal diffusing capacity, and evidence of air trapping on chest CT scans." (p. 152)

- "Of the lung biopsy reports we reviewed, two of three workers biopsied from plant A and three of six workers biopsied from plant E had findings consistent with constrictive bronchiolitis obliterans." (p. 152)

- "…ever-mixers had higher prevalences of all respiratory symptoms with statistically significant excesses for SOB 2, chronic cough, and wheezing (Table 3)." (p. 152)

- "The mean percent predicted FEVl was 89% in ever-mixers and 94% in never-mixers…" (p. 152)

- "Nine of the 10 ever-mixers with obstruction had a bronchodilator administered; eight of the nine (89%) had fixed obstruction." (p. 152)

- Tables 2 and 3 (p. 153)

- "Compared with packaging-area workers in plants with isolated tanks, packaging-area workers in plants with nonisolated or inadequately isolated tanks had higher prevalences of all respiratory symptoms and airways obstruction;..." (p. 153-154)

- Table 4 (p. 154)

- "Five of six QC workers tested (85%) had airways obstruction at plant A, which clearly had the highest QC laboratory mean diacetyl air concentration (0.6 ppm). No other plant had high rates of obstruction in QC workers." (p. 154)

- ". . . maintenance workers had higher prevalences of all respiratory symptoms…" (p. 154)

- Table 5 (p. 155).

- "The investigation of severe fixed obstructive lung disease in workers of a microwave popcorn plant in 2000 identified inhalation exposure to butter-flavoring chemicals as the likely cause." (p. 155)

- "Our analyses of aggregated data from medical and environmental surveys at the index plant and five additional microwave popcorn plants indicate an apparent widespread risk for occupational lung disease from exposure to butter-flavoring chemicals in this industry." (p. 155)

- "In five of six plants, mixers and/or packaging-area workers with onset of respiratory symptoms after starting work had undergone medical evaluations that revealed fixed airways obstruction and other findings consistent with bronchiolitis obliterans." (p. 155)

- "Mixers at four of six plants had medical findings consistent with bronchiolitis obliterans…" (p. 155)

- " . . . even when ventilation maintains low-average exposures, mixers are still at risk from brief, intense exposure associated with open handling of butter flavorings or opening lids to check on tanks of heated oil and flavorings." (p. 155-156)

- "Packaging-area workers near nonisolated tanks that contain heated oil and flavorings are likely at risk from higher average concentrations of flavoring chemicals in the air or from intermittent peak exposures when mixers add butter flavorings to tanks or lift tank lids to check on the contents." (p. 156)

- "The high prevalence of airways obstruction in QC workers at plant A implies that this job can pose risk when many dozens of bags are popped daily without adequate control of exposures. . . . However, the much higher temperatures that occur in microwave popping (compared with the temperatures in heated tanks) increase the volatilization of other chemicals. Because of this QC workers' exposures may be substantially different from those of other production workers, and diacetyl air concentrations alone may not be a satisfactory predictor of risk for these workers." (p. 156)

- "Of an estimated 425 former workers who worked at plant A between 1992 and 2000, I only 161 (approximately 38%) participated in our survey. Because of this low participation and the possibility that this was not a representative sample of former workers, we did not include this group in our analyses…" (p. 156)

- "At this time, insufficient data exist on which to base workplace exposure standards or recommended exposure limits for butter flavorings." (p. 156)

- "because flavorings are complex mixtures of many chemicals, most of which have not been evaluated with respect to inhalation toxicity, focusing solely on diacetyl air concentrations may not be adequate to assess risk in different plants using a variety of different flavorings." (p. 156)

- "Encapsulated powdered flavorings that release less flavoring-related vapors into the air may be a safer alternative to liquid and paste flavorings." (p. 157)

In addition, you requested the following:

1. Any and all data and documents submitted in connection with the peer review process for the Kanwal Article.

2. Any and all communications between DHHS, CDC, ATSDR or NIOSH or their respective agents, employees or representatives and the American College of Occupational and Environmental Medicine regarding the Kanwal Article.

3. Any and all inspections, investigations, evaluations, studies, reports, analyses, sampling, sampling data, files, questionnaires, measurements, pulmonary function tests ("PFT") (including but not limited to PFT results and all documents related to PFTs) or surveys (including but not limited to medical, environmental, and/or industrial hygiene), conducted by or on behalf of DHHS, CDC, ATSDR or NIOSH of the six plants that were the subject of the Kanwal Article.

4. Any and all correspondence, memoranda, meeting notes, or communications prepared at any time from 2000 to the present regarding any of the six plants that were the subject of the Kanwal Article or employees or former employees of the six plants.

5. Any and all photographs, videos, drawings, charts, and graphs regarding the six plants.

6. Any and all notices of violations, citations, and penalty notices issued by DHHS, CDC, ATSDR or NIOSH to any of the six plants,

7. Any and all records relating to the employees and former employees of the six plants who were the subject of investigation, evaluation, test or study, including but not limited to, medical records, medical histories, employment histories, job descriptions and occupational exposure histories.

8. All communications between DHHS, CDC, ATSDR or NIOSH or their respective agents, employees or representatives and any physician or other medical professional who examined, treated, consulted with or reviewed records of any employee or former employee of the six plants.

9. Any and all complaints, grievances, inquiries, or reports made, directed, forwarded to, or received by the DHHS, CDC, ATSDR or NIOSH related to the six plants.

10. Any and all correspondence or evidence of other communications (including but not limited to email, notes of conversations, and phone logs) between DHHS, CDC, ATSDR or NIOSH or their respective agents, employees, or representatives and any lawyer, doctor, or expert witness involved in or previously involved in litigation relating to diacetyl and/or butter flavoring at any time from 2000 to the present, including but not limited to David Egilman, M.D., Alan Parmet, M.D., Charles Pue, M.D., or Kenneth McClain, Esq. (or any other person affiliated with Humphrey Farrington & McClain).

11. Any and all records relating to long-term studies, follow-up investigations, evaluations, tests, studies, reports (including drafts and supporting or backup documentation or data) conducted by or on behalf of the DHHS, CDC, ATSDR or NIOSH of any popcorn plant worker, including but not limited to the employees or former employees of the six plants.

We located 9,411 pages of responsive records, which we are providing to you as Bates-numbered, certified PDF files on disk (4,986 pages released in full, 3,581 pages disclosed in part, and 844 pages withheld in full). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemptions (b)(4), (b)(5), and (b)(6).

Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. The information withheld is commercial or financial information, such as ingredients, staffing details, and production line details. We have determined that the individual/s to whom this information pertains have a substantial commercial or financial interest in withholding it.

Pursuant to the provisions of 5 U.S.C. §552(b)(4) of the Freedom of Information Act and 45 CFR §5.65 of the Department's implementing regulations, we are unable to reproduce the contents of documents which are protected by Title 17 U.S. Code, Section 106 of the Copyright Act. We are enclosing the first page of each document for your information in the event you wish to obtain these articles directly from the copyright owner.

Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under Exemption 5 was protected under the deliberative process and attorney-client privileges. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both

predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include draft documents (multiple drafts of the Kanwal article). The attorney-client privilege protects "confidential communications between an attorney and his client relating to a legal matter for which the client has sought professional advice" and is not limited to the context of litigation. The information that has been withheld under the attorney-client privilege of Exemption 5 constitutes confidential communications between agency attorneys and agency clients.

Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as names, addresses, and health information, and we have determined that the individual/s to whom this information pertains have a substantial privacy interest in withholding it.

In response to your request for documents containing "backup" for the subject manuscript (the "Kanwal Article") we located the following in response to each bullet:

- Pages 1 – 222 pertains to your 1st bullet.

- Pertaining to your 2nd bullet, program staff inform me that, as referenced in the article listed below, the subject statement was based on scientific findings conducted in the Health Effects Laboratory Division, NIOSH.

  Hubbs A, Battelli L, Goldsmith W, et al. Necrosis of nasal and airway epithelium in rats inhaling vapors of artificial butter flavoring. Toxicol Appl Pharmacol. 2002; 185:128 – 135.

- Pertaining to your 3rd bullet, program staff inform me that, as referenced in the article listed below, the subject statement was based on scientific findings conducted at the University of Cincinnati.

  Lockey J, McKay R, Barth E, Dahlsten J, Baughmen R. Bronchiolitis obliterans in the food flavoring manufacturing industry. Am J Respir Crit Care Med. 2002; 165 (suppl): A461.

- Pages 223 – 233 pertains to your 4th bullet.

- Pages 234 – 813 pertains to your 5th bullet.

- Pages 814 – 1,132 pertains to your 6th bullet. For further information, program staff inform me that NIOSH technicians used Ohio dry rolling seal spirometers, which interface with personal computers that have specialized software to analyze the breathing results, which follow the Third National Health and Nutrition Examination Survey III – Spirometry Procedure Manual (NHANES) guidelines

that are recommended by the American Thoracic Society. NIOSH's spirometry technicians are required to complete a NIOSH-approved training course that teaches spirometric theory and technique. They train with senior technicians both in the NIOSH laboratory and in the field prior to being approved for independent field-testing. Quality reviews are conducted to ensure that technicians are testing at high proficiency.

- Pages 1,133 – 1,307 pertains to your 7th, 33rd, and 34th bullets.
- Pages 1,308 – 1,491 pertains to your 8th, 20th, 21st, 33rd, and 34th bullets.
- Pages 1,492 – 1,719 pertains to your 9th bullet.
- Pages 1,720 – 1,899 pertains to your 10th bullet.
- Pages 1,900 – 2,049 pertains to your 11th bullet.
- A search of our records failed to reveal any documents pertaining to your 12th bullet. Program staff inform me that this was a visual observation made by NIOSH employees during the plant surveys, which revealed production processes and work practices similar to those of other popcorn plants.
- A search of our records failed to reveal any documents pertaining to your 13th bullet. Program staff inform me that this was a visual observation made by NIOSH employees during the plant surveys, which revealed production processes and work practices similar to those of other popcorn plants.
- A search of our records failed to reveal any documents pertaining to your 14th – 19th bullets. Program staff inform me that it appears the subject table was populated directly from the data presented in the original final reports of the six HHEs, and those numbers were supplemented with data provided by the individual lead industrial hygienists from each of the six HHEs.
- Pages 2,050 – 2,250 pertains to your 22nd – 31st bullets.
- Pages 2,260 – 2,269 pertains to your 22nd – 25th bullets.
- Pages 2,251 – 2,259 pertains to your 25th bullet.
- Pages 2,270 – 2,293 pertains to your 27th bullet.
- Pertaining to your 28th bullet, program staff inform me that the subject statement was taken directly from the reference below. The diacetyl concentrations mentioned in the statement and found in Table 6 are found in Table 2, page 333 of the article. Likewise, the statement that 5 of 6 quality workers had obstruction is stated at the bottom of paragraph 2 on page 333.

Kreiss K, Gomaa A, Kullman G, Fedan K, Simoes E, Enright P. Clinical bronchiolitis obliterans in workers at a microwave-popcorn plant. N Engl J Med. 2002; 347: 330-338.

- Pages 2,294 – 2,323 pertains to your 29th bullet.

- Pages 2,324 – 2,361 pertains to your 26th and 30th bullets.

- Pages 2,362 – 2,368 pertains to your 31st bullet.

- A search of our records failed to reveal any documents pertaining to your 32nd bullet. Program staff inform me this statement was derived from the program's analyses of the enclosed SAS codes and outputs formulated from the raw data collected from the six popcorn plants that were up to that point of the manuscript.

- A search of our records failed to reveal any documents pertaining to your 35th bullet. Program staff inform me that the subject conclusion was drawn from the results presented on Page 151. Plant D was found to have the lowest average personal diacetyl concentrations (probably due to their use of both local exhaust ventilation of the tanks and general dilution with outside air). Yet, real-time monitoring at plant D of a mixer's breathing zone during the time he poured liquid butter flavorings found peak diacetyl concentrations greater than 80 ppm.

- A search of our records failed to reveal any documents pertaining to your 36th bullet. Program staff inform me that the subject conclusion is drawn from the average diacetyl concentration data in packaging areas presented in Table 1 on page 151. The average concentrations (for both area and personal average diacetyl concentrations) was an order of magnitude lower for plants that had isolated their tanks (plants C, D, and F) when compared to the plants that did not have isolated tanks (plants A, B, and E).

- A search of our records failed to reveal any documents pertaining to your 37th bullet. Program staff inform me that the finding (presented in Table 6) of a higher prevalence of obstruction in Quality Control (QC) workers in plant A when compared to QC workers in plants D and F, and when compared to packaging workers in plants with both isolated and non-isolated tanks (presented in Table 5) led to the statement of this concern and their exposures, and therefore risk, might be different.

- A search of our records failed to reveal any documents pertaining to your 38th bullet. Program staff inform me that a complete roster of all former workers at plant A was not available from the company. The list of potential former workers was created by combining lists from several sources; therefore, the estimate of the total work force (n=425) was probably an underestimate. A common practice of good survey design is to minimize the effects of selection bias and avoid drawing

incorrect conclusions about the population under study by maximizing participation rates. Although there may be debate as to how to define a "good" participation rate, there is general consensus that a participation rate of ≤38% is problematic. The National Heart Lung and Blood Institute (NHLBI) guidance takes issue with participation rates below 50% when assessing the quality of cross-sectional studies (http://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/cohort).

- A search of our records failed to reveal any documents pertaining to your 39th bullet. Program staff inform me that NIOSH does not develop workplace exposure standards. NIOSH's policy for making a recommended exposure limit (REL) is as follows: "NIOSH recommended exposure limits (REL) will be based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques (see https://www.cdc.gov/niosh/topics/cancer/pdfs/1995_NIOSHRELpolicy.pdf). This manuscript reports the exposures and health outcomes observed during six cross-sectional surveys at microwave popcorn plants, but does not include the additional information required to develop a REL.

- A search of our records failed to reveal any documents pertaining to your 40th bullet. Program staff inform me that it is not possible to generalize the findings reported from these 6 cross-sectional surveys at manufacturing facilities using butter flavorings to workplaces that use a variety of flavorings with different chemical compositions and flavor profiles.

- A search of our records failed to reveal any documents pertaining to your 41st bullet. Program staff inform me that this manuscript summarizes sampling results from six facilities that used butter flavorings in a variety of forms (liquid, paste, and powder) and mixed into heated soybean oil (page 150) before being added to microwave popcorn bags. The subject statement hypothesizes that the use of encapsulated powdered flavorings, which are designed to release the majority of butter flavoring while the popcorn is popping, might lead to lower exposures to workers during the manufacturing process.

In response to your request for additional information, we located the following:

1. Pages 2,369 – 2,953

2. Pages 2,954 – 2,956

3. Pages 2,957 – 6,820

4 & 9. Pages 6,621 – 8,430

5. Pages 8,431 – 9,411

6. A search of our records failed to reveal any documents. Program staff inform me that there are no responsive documents related to any citations issued by CDC/ATSDR or NIOSH, as NIOSH does not issue fines or citations in the workplaces it evaluates.

7, 8, & 10. All additional records are included in our response to your request for "backup" information.

11. A search of our records failed to reveal any documents. Program staff inform me that at this time, no long-term studies have been conducted.

Documents belonging to the Department of Defense (2 pages), the Environmental Protection Agency (2 pages), and the Occupational Safety and Health Administration (6 pages) were found in our search. In accordance with the Department's implementing regulations, CDC does not make decisions on the release or denial of other agencies' documents. We have forwarded the records to the following for their release determination and direct response to you:

US Department of Defense
Office of Freedom of Information
1155 Defense Pentagon
Washington, DC 20301
Phone: (571) 372-0498

National Freedom of Information Officer
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460
Phone: (202) 566-1667

US Department of Labor - OSHA
Attn: FOIA Officer
200 Constitution Avenue, NW, Room N-3647
Washington, DC 20210
Phone: (202) 693-1999

Our July 5, 2018, supplemental response letter to your CDC FOIA request #12-00500 advised that we were reviewing the fee original invoices associated with that case to determine whether a partial refund of the fees you paid was justified. We have determined that a partial refund is justified. Therefore, we are waiving all fees associated with request #15-00285, amounting to $6,910.00 in total (see enclosed invoice).

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records

Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by December 5, 2018.

Sincerely,

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Information Officer
(770) 488-6399
Fax: (404) 235-1852

Enclosures

15-00285-FOIA